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# In the Supreme Court of the United States

OCTOBER TERM, 1995

ORTHO PHARMACEUTICAL CORP.,
PETITIONER,
*v.*
GENETICS INSTITUTE, INC. AND AMGEN INC.,
RESPONDENTS.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

## RESPONDENT GENETICS INSTITUTE, INC.'S BRIEF IN OPPOSITION

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## QUESTION PRESENTED

Whether the Court of Appeals for the Federal Circuit correctly interpreted a series of interrelated license agreements to find that the petitioner's patent license was nonexclusive and that, under well established law, a nonexclusive licensee such as the petitioner lacked standing to sue for patent infringement.

## STATEMENT PURSUANT TO RULE 29.1

The respondent Genetics Institute, Inc., is affiliated with American Home Products Corporation.

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## RESPONDENT GENETICS INSTITUTE, INC.'S BRIEF IN OPPOSITION

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The respondent Genetics Institute, Inc. ["Genetics"] respectfully requests that this Court deny the petition for writ of certiorari.

## STATEMENT

The petitioner incorrectly states that the Federal Circuit "effectively overruled" this Court's decision in *Independent Wireless Telegraph Co.* v. *Radio Corporation of America*, 269 U.S. 459 (1926). Both courts below fully acknowledged the validity of the relevant precedents — including *Independent Wireless* — and applied them to the facts of this case. The courts below did not rule explicitly (or "effectively") that an exclusive field-of-use licensee lacked standing to sue for patent infringement within

its licensed field. Rather, both courts concluded that the particular agreements at issue in this case did not make Ortho Pharmaceutical Corp. ["Ortho"] an exclusive patent licensee in the field in which the alleged infringement occurred.

The petitioner's characterization of this complex series of license agreements is thus at odds with the findings of both lower courts. Far from presenting the important and clear-cut issue of law asserted by the petitioners, the decisions below present no more than a factual dispute about the proper characterization of a particular arrangement between private parties, and as such does not warrant this Court's review.

The essential ruling of the Court of Appeals in disposing of the petitioner's claim was its determination that whatever patent rights were granted to Ortho were non-exclusive, and that whatever arguably exclusive rights were granted to Ortho were not patent rights, and thus could not confer standing in this patent suit:

> Ortho commingles its consent from Kirin-Amgen to sell EPO abroad . . . with the rights it received from Amgen under the U.S. patent to use the '008 technology. U.S. patent '008 provides no rights respecting the product EPO *per se*. . . . With respect to Ortho's right to sell unpatented EPO abroad, the [district] court correctly held that Ortho's right was not a proprietary right arising from the '008 patent. Indeed, Amgen itself had no right to sell EPO abroad by reason of its obtaining the '008 patent and, thus, could not license that right to Ortho as an incident of patent ownership. With respect to rights under the '008 patent, Ortho had only a nonexclusive right to use the '008 invention at one location in the United States. Thus, considering only this right, Ortho is a bare, that is, nonexclusive, licensee and has no standing to bring or join a suit for infringement against Genetics.

[App. A at A-15 (footnote omitted)]

Finally, Ortho fails to advert to an alternative ground for the ruling below, which effectively disposes of this suit without reference to the issues Ortho raises here.

A. *Factual Background*

Erythropoietin ["EPO"] is a hormone that stimulates the synthesis of red blood cells in bone marrow. As both lower courts recognized, Amgen Inc.'s United States Patent No. 4,703,008 [the "'008 patent"] does not cover the EPO product itself. [App. A at A-2; App. B at B-5]. Rather, the '008 patent claims a purified and isolated DNA sequence encoding human EPO and host cells transformed or transfected with a DNA sequence in a manner that allows the host cells to express EPO. In essence, the patent covers certain products (machines or starting materials) used to manufacture EPO, but does not cover the EPO product manufactured by those machines or starting materials.

In 1984, three years prior to the issuance of the patent, Amgen and Kirin Brewery Company established a joint venture, Kirin-Amgen, Inc. At the same time, Amgen, as owner of the then-pending application for the '008 patent, assigned certain rights to Kirin-Amgen. [App. A at A-2 - A-3].

In 1985, Amgen and Kirin-Amgen entered into separate Product License Agreements (PLAs) with Ortho. Those PLAs addressed much more than the '008 patent: they granted not only certain patent rights under the '008 patent, but also certain *foreign* patent and *contractual (i.e.,* non-patent) rights.

Section 2.01(b) of Ortho's license agreement with Amgen provided the basis for Ortho's claim of standing before the Federal Circuit:

> AMGEN, having received the consent of Kirin Brewery Co., Ltd., hereby grants to ORTHO but not AFFILIATES, an exclusive license, except as against AMGEN's rights under this AGREEMENT in the LICENSED TERRITORY, to make EPO in one location

> in the United States for use and sale outside the LICENSED TERRITORY but not including China and Japan. . . .

[App. A at A-4].[1] The agreement defined the LICENSED TERRITORY as the United States. [*Id.* at A-4 - A-5].

The PLA executed by Ortho and Amgen also contained section 8.02, entitled "Infringement by Third Parties," which provided:

> AMGEN shall have the right, but not the obligation, to bring, defend, and maintain any appropriate suit or action. . . . In the event AMGEN fails to take actions with respect to such matters within a reasonable period, not more than six (6) months, following receipt of such notice and evidence, ORTHO shall have the right, but not the obligation, to bring, defend, and maintain any appropriate suit or action.

[App. A at A-15 - A-16].

From Kirin-Amgen, Ortho obtained (1) an "exclusive license" to *sell* throughout the world (except for the United States, China, and Japan) EPO manufactured by using the inventions claimed in the '008 patent for all human uses except diagnostics, and (2) the right to use the inventions claimed in the '008 patent to *manufacture* EPO in one location in the United States for *sales everywhere outside* the United States

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[1] Section 2.01(a) of the Amgen PLA provided:

> AMGEN hereby grants to Ortho but not AFFILIATES, except as hereinafter provided, an exclusive license to make in one location, have made and use LICENSED KNOW-HOW, LICENSED PATENTS and LICENSED PRODUCTS in the LICENSED TERRITORY in the LICENSED FIELD and to sell LICENSED PRODUCTS in the LICENSED TERRITORY.

As discussed below, Ortho expressly abandoned reliance on Section 2.01(a) before the Federal Circuit and, thus, only Section 2.01(b) of the PLA is presently at issue in this case. *See* Note 6, *infra*.

(except China and Japan) for all human uses except diagnostics. [App. B at B-5 - B-6].

On October 27, 1987, the date the '008 patent issued, Kirin-Amgen assigned the patent to Amgen and Amgen brought suit for infringement against Genetics. The trial was bifurcated into liability and damages phases. After a year and a half of discovery, the trial on liability was scheduled to begin on August 7, 1989. [App. C at C-4]. On March 17, 1989, Ortho moved to intervene in that action. [*Id.*]. That motion was denied on grounds of untimeliness and because Ortho's interests regarding liability were adequately represented by Amgen. [App. C at C-1 and C-12]. Ortho did not appeal that decision.

Following a bench trial on liability, certain claims of the '008 patent were found to be valid and enforceable and to be infringed by Genetics' use of the '008 invention to manufacture EPO in the United States. *Amgen Inc.* v. *Chugai Pharmaceutical Co., et al.*, 13 U.S.P.Q.2d 1737 (D. Mass. 1989).[2] The Federal Circuit affirmed the judgment on the '008 patent on interlocutory appeal. *Amgen Inc.* v. *Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir.) *cert. denied*, 502 U.S. 856 (1991).[3]

Ortho and its European licensees then filed suit against Genetics in the district of Massachusetts seeking damages for lost profits on foreign sales of the unpatented EPO product.[4] Ortho's suit was consolidated with Amgen's suit. Both the patentee Amgen and Genetics filed motions to dismiss or for summary judgment against Ortho on the grounds that Ortho lacked standing.

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[2] The district court also found that Genetics' infringement of the '008 patent was not willful and that Genetics' patent relating to EPO was valid and infringed by Amgen. *Id.* at 1739.

[3] The Federal Circuit, however, reversed the district court's judgment relating to the validity of Genetics' EPO-related patent.

[4] Ortho also filed suits against Genetics' licensee in various European countries seeking the same damages for the same transactions under foreign patents relating to EPO.

B. *The District Court's Decision on Standing*

The district court granted the motions to dismiss Ortho for lack of standing.[5] In so doing, the court expressly recognized the rule of *Independent Wireless* that an exclusive patent licensee has standing to sue for patent infringement in its stated area of exclusivity. [App. B at B-11 - B-12]. The district court also recognized, however, that "a mere non-exclusive licensee has no standing to sue for infringement," and that it was therefore necessary to examine the precise language of the license agreements to determine whether those agreements actually granted Ortho exclusive use of any portion of the '008 patent. [App. B at B-12 - B-13]. The court correctly noted that this issue should be determined by the substance of those agreements rather than by their use of the label "exclusive license." [App. B at B-5].

The district court then turned to Ortho's argument that section 2.01(b) of the Amgen PLA granted Ortho an exclusive field-of-use license to use the '008 patented inventions in the United States to make EPO for the purpose of sale abroad.[6] After considering in detail the various provisions of Ortho's PLAs with both Amgen and Kirin-Amgen, the district court concluded that, although Ortho may have received an exclusive contractual right under those agreements to export the *unpatented* EPO product, it did not receive an exclusive right to use any portion of the '008 patent itself; thus, the district court concluded that Ortho was not an exclusive licensee with standing to sue for any infringement of the '008 patent. [App.

[5] Prior to the ruling by the district court, the underlying Amgen/Genetics litigation was settled. [App. A at A-18].

[6] The district court had also rejected Ortho's argument that standing could be premised on Section 2.01(a) of its PLA with Amgen. [App. B at B-15 - B-17]. Ortho expressly abandoned this Section 2.01(a) argument on appeal. [App. A at A-12].

B at B-17 - B-21].[7] On this basis,[8] the district court granted Genetics and Amgen's motion.

### C. *The Federal Circuit's Decision on Standing*

After independently examining the variously intertwined provisions of the Amgen and Kirin-Amgen PLAs, the Federal Circuit unanimously affirmed the district court's conclusion that Ortho's only exclusive right was the right to sell EPO abroad, which is not a right under the '008 or any other United States patent. Instead, the exclusive right to sell the unpatented EPO product abroad was a *contractual* right. In short, the Federal Circuit concluded that Ortho's section 2.01(b) argument for standing erroneously "commingles its consent from Kirin-Amgen to sell EPO abroad ... with the rights it received from Amgen under the U.S. patent to use the '008 technology." [App. A at A-14].

Repeatedly relying on *Independent Wireless* [*see, e.g.*, App. A at A-11, A-16, and A-17], the Federal Circuit first

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[7] In its petition Ortho contends that "the district Court stated: '[Ortho holds] an "exclusive license" to use the invention claimed in the '008 patent for the manufacture of EPO ... in the U.S. ... for the sale outside the U.S.'." As support for its contention, Ortho cites App. B at B-16. At that point in its opinion, however, the district court was reciting the language of the PLA; the quoted language was not a finding by the district court that the PLA granted an exclusive field-of-use under the '008 patent. As the district court expressly noted, "both PLA's use the words 'exclusive license' to describe the rights Ortho obtains from Kirin-Amgen and Amgen respectively. Whether these words have the legal effect of making Ortho an exclusive licensee under patent law, however, is a question the Court resolves *infra*. ..." [App. B at B-5].

[8] Although Ortho argued to the Federal Circuit (and continues to argue to this Court) that the basis for the district court's decision was the "bizarre and unprecedented theory" that a field-of-use license "somehow 'exceeds the scope of the ... patent' and therefore cannot provide a basis for standing." Petition at 10, the Federal Circuit properly recognized that this argument is based on a fundamental misreading of the district court's opinion. "Contrary to Ortho's argument, the court held only that the provision respecting foreign sales of EPO was a contract right, not that the agreement was unenforceable against Amgen." [App. A at A-15 n. 7].

noted that the question of licensee standing was a highly fact-dependent inquiry:

> Co-plaintiff standing is determined by whether or not the licensee acquired proprietary rights in the patent under the contract with the patentee. . . . To resolve the issue of standing, we must examine the licensing agreement to determine whether the parties intended to effect a transfer of proprietary rights to the licensee as an incident to protection of its interests.

[App. A at A-12]. In making this factual inquiry the Federal Circuit accepted as true all material allegations of Ortho's complaint, which it construed in Ortho's favor. [App. A at A-13].

The Federal Circuit next turned to a detailed examination of the various license agreements. The Federal Circuit noted that it was "undisputed" that, with respect to patent rights, Ortho's implied license to use the '008 invention in one location in the United States "was nonexclusive inasmuch as Amgen had the right to license others to do the same." [App. A at A-14]. As the Federal Circuit summarized Ortho's argument, "Ortho concedes this point but argues that its additional right to sell EPO abroad as provided in paragraph (b) is an exclusive field of use of the '008 technology which provides standing." [*Id.*]

The Federal Circuit rejected this argument because of Ortho's failure to distinguish between the exclusive contract (*i.e.*, non-patent) rights that Ortho received and the nonexclusive U.S. patent rights it received.

> U.S. Patent '008 provides no rights respecting the product EPO *per se*. Moreover, a U.S. patent grants rights to exclude others from making, using, and selling the patented invention only *in the United States*. . . . With respect to Ortho's right to sell unpatented EPO

> abroad, the [district] court correctly held that Ortho's right was not a proprietary right arising from the '008 patent.

[App. A at A-14 - A-15] (emphasis in original).

Based on the various provisions of the PLAs, the Federal Circuit ultimately concluded that,

> with respect to rights under the '008 patent, Ortho had only a nonexclusive right to use the '008 invention at one location in the United States. Thus, considering only this right, Ortho is a bare, that is, nonexclusive, licensee and has no standing to bring or join a suit for infringement against Genetics.

[App. A at A-15].[9]

## REASONS WHY THE PETITION SHOULD BE DENIED

### A. *Neither the decision below nor the record raises the Questions Presented in the petition*

Ortho suggests that this case presents the "important question" of "whether the holder of an exclusive license to practice a patent in a particular field-of-use has standing to sue for acts of infringement in that field-of-use. . . ." Petition at 3. In fact, however, the petitioner's proffered question was not presented at all by the facts of this case. To the contrary,

[9] Ortho now urges that this decision was at odds not only with *Independent Wireless*, but also with a series of decisions in the Federal Circuit and other courts of appeal. Ortho, however, failed to seek *in banc* reconsideration by the Federal Circuit, which is the usual manner in which intra-circuit conflicts within the Federal Circuit are clarified. *See* Fed.R.App. P. 40 (providing that a petition for rehearing may be filed when a party believes that the appeals court has "overlooked or misapprehended" a point of law); Federal Circuit Practice Note to Rule 40 (authorizing the filing of a suggestion for rehearing *in banc*).

both the district court and the Federal Circuit accepted and applied the rule of law that the petitioner asks this Court to reaffirm on certiorari — that is, that exclusive field-of-use licensees do have standing.

The legal right of an exclusive field-of-use licensee to sue for infringement was never at issue below. Rather, under the facts of this case, both lower courts found that because Amgen retained the right to use the '008 patent and the unfettered privilege to sublicense that right, Ortho was not an exclusive licensee. Well settled legal principles make it clear that if Ortho is a nonexclusive licensee, it does not have standing to sue for patent infringement; the petitioner does not contend otherwise. Not only is the Federal Circuit's decision thus not contrary to *Independent Wireless*, it endorses the central tenet of that case, as stated by the petitioner itself: a field-of-use licensee shall have standing to sue if, and only if, "the license confers exclusive rights in that particular field" under the patent. Petition at 3. As both lower courts found, Ortho's license does not.

Moreover, there can be no doubt that the Federal Circuit considered itself bound by (and to be applying) *Independent Wireless*. Its opinion repeatedly cites, quotes, and relies on this Court's opinion in that case. [*See, e.g.*, App. A at A-11, A-16, and A-17]. Indeed, the Federal Circuit has consistently applied *Independent Wireless* elsewhere, both before and after its decision in this case. *See, e.g., Abbott Laboratories* v. *Diamedix Corp.*, 47 F.3d 1128, 1131 (Fed. Cir. 1995); *Rite-Hite Corp.* v. *HMH Co.*, 56 F.3d 1538, 35 U.S.P.Q.2d 1065, 1074 (Fed. Cir. June 15, 1995). Thus, the contention by the petitioner that the Federal Circuit has effectively "overruled" *Independent Wireless* is baseless.

The petitioner further urges that this case presents the question whether the measure for standing for a field-of-use licensee is the exclusivity of its rights with respect to (a) the entirety of the "use" right covered by the patent, or (b) the particular field-of-use where the acts of infringement occurred. Yet, that question was not at issue in this case, either.

The '008 patent gave Amgen the right to exclude Genetics from using the patented technology in the United States; the *patent* conferred no rights regarding the sale of the unpatented EPO product abroad. Thus, the patent was found to be infringed by Genetics' use of the '008 invention *in the United States*, where Ortho's patent rights are nonexclusive. Indeed, Ortho expressly "concede[d]" that its implied right to use the '008 invention was nonexclusive. [App. A at A-14].

The essence of Ortho's argument below was that certain exclusive *non-patent* rights granted to Ortho by Kirin-Amgen could create a field of exclusivity within Ortho's admittedly nonexclusive *patent* rights from Amgen. Both lower courts correctly rejected this argument under the facts of this case. As both lower courts concluded, Ortho's exclusive rights were not derived from the '008 patent, but rather were the product of commingling Ortho's contract rights and its nonexclusive patent rights. [App. A at A-14; App. B at B-21].

Thus, the Questions Presented proffered by the petitioner are simply not raised by the facts of this case or the holdings of the courts below.

B. *The petition asks this Court to reinterpret complex and fact specific licensing provisions despite consistent interpretation by both courts below*

The licensing provisions at issue are complex, interrelated, and highly fact specific, involving two different licensors, both with different sets of U.S. and foreign patent and non-patent rights to license. Two courts have already worked their way through these licensing provisions and arrived at the same factual conclusion: that the license grant to Ortho was nonexclusive under the '008 patent. In arriving at that factual conclusion, the Federal Circuit did not purport to establish a new rule of law or, indeed, any rule of general applicability beyond the specific facts of this case.

Ortho now asks this Court to work through these provisions yet a third time. There is, however, nothing in the petition

or in the decisions below to indicate that this Court would arrive at anything other than the same conclusion: that, under the licensing provisions at issue in this case, Ortho received only a nonexclusive license under the '008 patent. This highly fact-specific determination by the courts below is not worthy of review by this Court. *See, e.g., Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 336 U.S. 271, 275 (1949) ("a court of law, such as this Court is, rather than a court for correction of errors in fact finding, cannot undertake to review concurrent findings of fact by two courts below in the absence of a very obvious and exceptional show of error").[10]

C. *The petition ignores the unique role of the Court of Appeals for the Federal Circuit*

Although the petitioner suggests that its petition should be granted "[b]ecause the Federal Circuit hears all appeals in patent cases," Petition at 16, the Federal Circuit's exclusive jurisdiction over patent appeals in fact provides an additional reason for denying the petition. Indeed, the Federal Circuit was established in large part to bring expertise and uniformity to patent law. *See* House Rep. No. 97-312, 97th Cong., 1st Sess. (1981) at 20-23.

In this case, the Federal Circuit did precisely what it was supposed to do: it took general principles as mandated by this Court and applied them to a case-specific tangle of facts. The result reached by the Federal Circuit in this matter upholds all of the policy considerations underlying the law of standing in patent infringement suits, including the policies:

- that the patent owner (here, Amgen) has the paramount interest in selecting the forum for defending its patent;

[10] Even if the points raised in the petition were valid and worthy of certiorari, they would not dispose of this case. This matter would need to be remanded for consideration of section 8.02 of the PLA, not reached by the Federal Circuit. In that section of the PLA, Ortho bargained away to Amgen any right Ortho may have had to bring a suit against infringers, *even if* Ortho had standing.

- that the accused infringer (here, Genetics) should not be subjected to multiple suits resulting from the same act; and
- that economic injury alone is insufficient to support standing in a nonexclusive licensee.

*See, A.L. Smith Iron Co.* v. *Dickson*, 141 F.2d 3, 6 (2d Cir.1944) (L. Hand, J.) [*quoted favorably in* App. A at A-9 - A-10]. *See also, Site Microsurgical Systems, Inc.* v. *Cooper Companies, Inc.*, 797 F.Supp. 333, 337 n.8, 24 U.S.P.Q.2d 1463, 1466 n.8 (D. Del. 1992); *Schneider (Europe) AG* v. *SciMed Life Systems, Inc.*, 28 U.S.P.Q.2d 1225, 1229 (D. Minn. 1993).

D. *The Federal Circuit had alternative grounds for its decision not included in the petition*

In the final paragraph of its opinion, the Federal Circuit held that:

> Ortho does not claim it was a necessary or indispensable party to Amgen's suit, did not appeal the denials of intervention therein, and did not appeal the order deconsolidating this suit from Amgen's. Moreover, the parties advised the Court at the hearing that the Amgen/Genetics litigation has been settled. Thus, Ortho has effectively consented and concurred to suit in the name of the patentee alone.

[App. A at A-18].

Thus, the Federal Circuit found that, even if Ortho's arguments for co-plaintiff standing had any merit, those arguments have been waived by Ortho's effective consent and concurrence in Amgen's lawsuit. This fully independent, alternative ground for the Federal Circuit's decision was not included in the petition for certiorari and thus presents yet another reason for its denial.

## CONCLUSION

For these reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted,

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